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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/722,441	11/28/2000	Paul D. Hanke	1533.1030002/SRL/SEZ	4696

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EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 12/17/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/722,441

Applicant(s)

HANKE ET AL.

Examiner

Kathleen M Kerr

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 23 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 30-60 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-7, 10-15, 17-24, 27-29, 61, 62 and 64-69 is/are allowed.
- 6) ☒ Claim(s) 8, 9, 16, 25, 26 and 63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. In response to the previous Office action, a first Office action on the merits (Paper No. 13, mailed on May 22, 2002), Applicants filed an amendment and response received on September 23, 2002 (Paper No. 17). Claims 1-67 are pending in the instant Office action. Claims 1 and 30-60 are withdrawn from consideration as non-elected inventions. Claims 2-29 and 61-67 will be examined herein.

Priority

2. As previously noted, a request for the benefit of priority for the U.S. Provisional Application Nos. 60/173,707, filed on December 30, 1999, and 60/184,130, filed on February 22, 2000, as requested in the first lines of the specification, is acknowledged.

Information Disclosure Statement

3. The reference previously noted as missing from the information disclosure statement filed on June 22, 2001 (Paper No. 4), Zupancic, has been filed and the reference has been initialed on the IDS. A copy is attached hereto. All references in three IDS forms filed have now been considered.

Drawings

4. As previously noted, the formal drawings filed on June 22, 2001 (Paper No. 5) have been approved by the Draftsmen and are, therefore, entered as formal drawings acceptable for publication upon the identification of allowable subject matter. Also, the substitute drawing (Figure 13) filed on September 23, 2002 is also considered formal and ready for publication.

Compliance with the Sequence Rules

5. By virtue of Applicants' amendment (Paper No. 17) to the specification in the Brief Description of the Drawings, the instant application now fully complies with the sequence rules.

Withdrawn - Objections to the Specification

6. Previous objection to the specification because of informalities and/or lack of clarity is withdrawn by virtue of Applicants' amendments to the specification and/or the drawings.

Maintained - Objections to the Specification

7. Previous objection to the specification because the title is not adequately descriptive is maintained. Applicants have amended the title adding only the use of Coryneform to the title. The claims are specifically drawn to the use of a feedback resistant aspartokinase from *Corynebacterium* and the claims must reflect this. Appropriate correction is required. (see M.P.E.P. § 606.01). As before, the Examiner suggests the following new title:

--Polynucleotides Encoding a Feedback Resistant Aspartokinase from *Corynebacterium*--

8. Previous objection to the specification because the abstract does not adequately describe the disclosed subject matter (see M.P.E.P. § 608.01(b)) is maintained. Applicants have amended the abstract, but a crucial piece of disclosed information is still missing. As previously noted, particular inclusion of a description of the novel *ask* mutant, that is an aspartokinase wherein "the naturally occurring threonine amino acid residue 380 in the feedback sensitive form is changed to isoleucine in the *ask* gene of ATCC 21529" (see page 4, lines 10-13 for support) is required for completeness. Appropriate correction is required.

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Withdrawn - Claim Objections

9. Previous objection to Claims 2-29 and 61-67 for depending from a non-elected claim is withdrawn by virtue of Applicants' amendment to Claim 2.

10. Previous objections to Claims 8-10, and 27 because of informalities are withdrawn by virtue of Applicants' amendments.

Withdrawn - Claim Rejections - 35 U.S.C. § 112, second paragraph

11. Previous rejection of Claims 6-15 under 35 U.S.C. § 112, second paragraph, as being indefinite for the antecedent basis of the phrase "**said** amino acid biosynthetic pathway genes" is withdrawn by virtue of Applicants' amendment removing said phrase.

12. Previous rejection of Claims 6-15 under 35 U.S.C. § 112, second paragraph, as being indefinite for definition of the term "amino acid biosynthetic pathway genes" is withdrawn by virtue of Applicants' amendment removing said phrase. Applicants argue the issue, but the amendment is sufficient to overcome the rejection.

13. Previous rejection of Claims 7 and 9 under 35 U.S.C. § 112, second paragraph, as being indefinite for the relative term "increased" is withdrawn by virtue of Applicants' amendment removing the term. Applicants argue the issue, but the amendment is sufficient to overcome the rejection.

14. Previous rejection of Claim 63 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "**the** LysA gene" (emphasis added) is withdrawn by virtue of Applicants' amendment removing this term. However, unclear language has been added; see new rejections below.

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Maintained - Claim Rejections - 35 U.S.C. § 112, second paragraph

15. Previous rejection of Claims 8, 9, 16, 25, and 26 under 35 U.S.C. § 112, second paragraph, as being indefinite for the terms “ ‘lysA” and “ORF2” is maintained. Applicants’ arguments have been fully considered but are not deemed persuasive. Applicants argue that the terms are defined clearly on page 5 and on page 14, respectively. The Examiner disagrees. No function is described in these pages of the specification. As previously noted, a function of a named enzyme is crucial in the discernment of the metes and bounds of its nature. As noted previously,

“Claims 8, 9, 16, 25, and 26 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claims 8 and 16, the terms “ ‘lysA” and “ORF2” are unclear as they refer to either amino acid sequences (Claim 8) or polypeptides (Claim 16). The terms “ ‘lysA” and “ORF2” refer to a genus of amino acid sequences or polypeptides. While a single species of each ‘lysA and ORF2 are defined by structure (amino acid sequence) in the figures, no function of these sequences is defined. The Examiner notes that the other genes names in the instant claims are functionally defined in Figure 1. Absent a functional definition of ‘lysA (the truncated form of lysA that is a diaminopimelate decarboxylase according to Figure 1) and ORF2, the very nature of this genus of amino acid sequences or polypeptides is wholly unclear when claimed by name alone. Appropriate clarification is required.”

Withdrawn - Claim Rejections - 35 U.S.C. § 112, first paragraph

16. Previous rejection of Claims 22-24, 27-29, and 66 under 35 U.S.C. § 112, first paragraph, enabling deposit, is withdrawn by virtue of Applicants’ amendment to the specification, Applicants’ statement of irrevocability of deposit upon the granting of a patent, and Applicants’ depositing particular plasmids.

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17. Previous rejection of Claims 61, 63-65, and 67 under 35 U.S.C. 112, first paragraph, written description, is withdrawn by virtue of Applicants' amendment to include a function with the structure claimed.

Maintained - Claim Rejections - 35 U.S.C. § 112, first paragraph

18. Previous rejection of Claims 8, 9, 16, 25, and 26 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive. Applicants argue that all the polynucleotides encoding *asd*, *dapB*, *ddh*, *lysA*, *lysA*, and ORF2 have been demonstrated in Figure 1, have been described in constructs on page 39, and have been deposited and that all these taken together represent adequate written description of the claimed invention. The Examiner disagrees that these examples demonstrate adequate written description for the instant claims. As previously noted,

“These polypeptides are functionally described in the specification in Figure 1 (except for *lysA* and *ORF2* as noted in a previous rejection). Moreover, a single species of each of these polypeptides (except for *lysA* with disclosed two species) is structurally described in the figures. Thus, a single species (or two in the case of *lysA*) of the genus of each named gene is fully described. However, a description of the common characteristics of each genus, particularly a correlation between the structure and function of these genes, is lacking in the specification. Without such a correlation, one of skill in the art would be unable to identify other members of each genus in structural and functional terms. In particular, the structure of the other members of each genus is unpredictable based on the description in the specification. For these reasons, Claims 8, 9, 16, 25, and 26 lack adequate written description. The Examiner suggests canceling the instant claims and relying on claims that cite specific SEQ ID NOs for the noted lysine biosynthetic pathway genes.”

Thus, it is clear from the previous rejection that a single species of the claimed genus does not adequately describe the genus as argued by Applicants.

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NEW REJECTIONS

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

19. Claim 63 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “operably directly linked to the encoded polypeptide sequence” is unclear since a promoter is typically linked to a polynucleotide sequence. The Examiner suggests the following substitute phrase ---operably linked to the nucleotide sequence encoding SEQ ID NO:2---.

Summary of Pending Issues

20. The following is a summary of the issues pending in the instant application:
- a) The specification stands objected to for an inadequately descriptive title.
 - b) The specification stands objected to for an inadequately descriptive abstract.
 - c) Claims 8, 9, 16, 25, and 26 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the terms “‘lysA” and “ORF2”.
 - d) Claim 63 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “operably directly linked to the encoded polypeptide sequence”.
 - e) Claims 8, 9, 16, 25, and 26 stand rejected under 35 U.S.C. § 112, first paragraph, written description.

Attention to **all** the above issues is required in response to the instant Office action to be fully responsive to this communication.

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Allowable Subject Matter

As previously noted, Claim 2 is drawn to a polynucleotide molecule encoding a mutant aspartokinase gene (the polypeptide SEQ ID NO: 2 is encoded by the polynucleotide SEQ ID NO: 1), which differs from the wild-type *Corynebacterium glutamicum* sequence at position 380 (T380I). This mutation renders the aspartokinase more resistant to feedback inhibition by lysine than the wild-type enzyme. This mutant gene was isolated from ATCC 21529, which strain is described in USPN 3,708,395 (Nakayama *et al.* 1973, IDS ref. AF1). While numerous *C. glutamicum* aspartokinase lysine-feedback-resistant mutants are known, for example see EP 0 854 189 A2 (IDS ref. AM1), the T380I mutation in *C. glutamicum* described in the instant application is novel and not obvious in view of the prior art. The novelty of a polynucleotide encoding SEQ ID NO: 2 governs the novelty of all the pending claims. All other specific examples of lysine biosynthetic pathway genes described in the figures are known in the art. The promoter of SEQ ID NO: 17 is also known as an endogenous promoter of the *lysA* gene in *C. glutamicum* (see Marcel *et al.* IDS ref AS5).

Conclusion

21. Claims 8, 9, 16, 25, 26 and 63 are rejected. Claims 2-7, 10-15, 17-24, 27-29, 61, 62, and 64-69 are allowed. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

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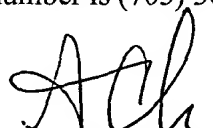
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK
December 12, 2002


KATHLEEN M KERR
EXAMINER
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